

REMARKS

Applicant has amended claims 36 and 37 to resolve the § 112 issues raised in the previous action. These amendments appear to resolve all outstanding issues under 35 U.S.C. § 112.

With respect to co-pending application serial no. 08/879,220, as noted in the previous response, Applicants may traverse the double patenting rejection with a terminal disclaimer, if appropriate, given the provisional nature of the rejection.

With respect to USP No. 6,294,166, the pending claims recite a product maintained as a granular, dry mixture in a sealed container. This element of the pending claims is not recited or suggested by the claims of the '166 patent. Thus the pending claims are separately patentable.

The Combination of Cajigas, Gonzalez, Barbarrau, Levy Prescott et al., Fletcher et al. and Merck Further Taken with Jolly and Friend et al. Is Not a Proper Combination Upon Which to Reject the Pending Claims Under § 103(a) -- the Proposed Combination Changes the Basic Principle of at Least the Jolly and Friend References.

As in the previous action, Applicant notes that the issues under § 103 have been significantly clarified and that all of the issues under § 112 appear to be resolved by the above amendments.

Although the Examiner has noted isolated instances in the several references cited whereby individual components of the claimed invention are used, 35 U.S.C. § 103 dictates that the cited prior art references must be considered "as a whole" and must suggest the desirability and thus the obviousness of making the combination. Furthermore, the combination used to establish a prima facie case under § 103 must not change the basic principles of operation of the prior art reference

relied on. In this case, the Examiner's position, that attempts to overcome the failure of the references to disclose a dry admixture of the components of the claimed compositions, is contrary to law. Any combination that includes Jolly (USP 4,107,334) and Friend necessarily yields a wet composition. Where the references used by the PTO in a combination § 103 rejection yield a wet composition, a feature directly contrary to the subject matter of the pending claims, the PTO cannot simply refer to a reference disclosing a dry composition to eliminate the wet feature that necessarily results from the very combination constructed by the PTO.

The reference selected by the PTO for the § 103 rejection, Jolly (USP 4,107,334), uses water or a water-based liquid in every example of the modified protein described therein. For example, Example 1 states: "a portion (32.7g) of the wet heat-denatured whey protein solids (10.1g dry) was dispersed in 100ml water." Example 2 states: "a portion (10g) of the heat denatured whey protein solids was dispersed in 90ml water." See also Examples 4-7 (column 7 at line 15). Example 8 states: "*S. cerevisiae* yeast cells (800g wet, 172g dry) were dispersed in a 1000ml water ..." and "The resulting slurry was centrifuged and the centrifuged cake was washed with water to yield 392g wet heat-denatured yeast protein solids (72g dry)." Example 9 states: "A sample of 200g of dry heat-denatured *S. cerevisiae* yeast protein solids was slurried in 1000ml effanol, filtered and washed with water." Example 10 states: "The wet heat-denatured soy protein solids was slurried in 300ml water." Example 11 states: "A 50g sample of dry soy whey solids was dissolved in 150ml water." A major component in Example 12 is water (see column 9, line 20). Similarly, Example 13 contains all of vinegar, vegetable oil, and water (see column 9, lines 47, 53 and 57). Example 14 discloses boiling water, and states: "The boiling water was added to the pre-blended dry ingredients and the mixture was whipped..." See column 10, lines 29 and 30. Finally, each of Examples 15 through 28 disclose water (See column 10, line 66; column 11, lines 34, 38-45; column 12, lines 15, 48, 51;

column 13, lines 17, 51; column 14, lines 25, 29-33, 65; column 15, lines 27, 59; column 16, lines 19, 50, 51-56; column 17, line 39; and disclose column 18, line 4. Thus, the result of the PTO's own proposed combination does not fairly disclose the dry, granular admixture element of pending claim 1 and this combination cannot yield a prima facie case of obviousness under 35 U.S.C. § 103(a).

The Prescott reference describes brewer's and baker's yeast in terms of production and protein content. Prescott also describes the use of brewer's yeast in animal feed and baker's yeast in dietary supplements. According to Prescott, brewer's yeast comprises about 40 % protein, and baker's yeast comprises about 50-55% protein. Prescott does not describe yeast as a particularly concentrated source of protein.

The Friend reference discusses the beneficial properties of *Lactobacillus* cultures, in general, including their nutritional and therapeutic benefits. As with Jolly, the Friend reference discloses only the administration of *Lactobacillus* in wet cultured dairy products, specifically yogurt and milk. The Friend reference does not mention a dried admixture containing yeast and bacteria, such as *Lactobacillus*, and does not suggest combining *Lactobacillus* and whey protein concentrate.

Considering the references in combination, none of the references can cure the defect in Levy such that a protein concentrate may be added to the disclosed formulation. The claimed compositions comprise a protein concentrate. Applicants submit that the plain meaning of this term for one of ordinary skill in the art is a relatively purified form of protein, rather than a "source" of protein. Thus, the third claimed component does not encompass powdered milk, blood meal, sawdust containing moderate amounts of lignin, or other putative "sources" of protein. The Jolly and Prescott references are offered in combination with the Levy reference to remedy the lack of a protein concentrate in the disclosed formulation. As mentioned above, the claimed protein concentrate is distinct from a mere "source" of protein. Thus, the assertion that the Prescott and

Jolly references teach that yeast contains protein, and is thus equivalent to the “protein” in the compositions utilized in the claimed methods, does nothing to remedy the lack of a protein concentrate in the Levy reference when compared to the claims compositions.

Furthermore, neither the Friend nor the Jolly reference suggests the addition of a protein concentrate to a bacteria and yeast composition. The Friend reference provides no impetus to add a protein concentrate to the compositions described in Levy, or to modify them in any other way. Friend does not describe nor suggest any methods of prolonging the viability of *Lactobacillus* cultures in dried bacterial compositions, nor does Friend even describe any such compositions. The Friend reference describes the use of bacterial cultures in milk and yogurt, neither of which is a protein concentrate. As described above, the general teachings of Friend that *Lactobacillus* cultures are “desirable” additions to nutritious product is not a sufficient motivating suggestion for one of ordinary skill in the art to make the specific combination of the claimed proportions of bacteria, yeast, and protein concentrate.

In addition to the failure of the references as a whole to teach the dry admixture, the specific concentrations and the protein concentrate component are not fairly disclosed by the references either alone or in combination. In the Office Actions, the Examiner recognizes that the Brewer’s yeast component recited in the claims is lower in concentration than that disclosed in the prior art, the Examiner also cites the beneficial nature of the yeast composition. However, the Examiner cites no basis or rationale why one skilled in the art would lower the concentration to arrive at the claimed percentages as part of an alleged “optimization” of the components. The rationale proposed to render the claimed composition obvious as a result-effective optimization of parameters is directly opposite to what the alleged optimization would produce. See In re Antonie, 195 USPQ 6, 8 (CCPA

1977). The Examiner has cited no authority to optimize the yeast concentration parameter in this fashion.

Therefore, the removal of water from a teaching of a formulation that is water-based would render the art unsatisfactory for the intended purpose. Further, with respect to the total mass percentages, a prior art reference describing a composition of matter with similar parameters will only render a claimed similar composition obvious by "optimization" of the parameters if the parameter was art recognized as result-effective. In Re Antonie 195 USPQ 6 (CCPA 1977) (See MPEP § 2144.05, II. B.). This is not the case here.

Applicant submits that the pending claims are in a position to be allowed.

Respectfully submitted,

ORRICK, HERRINGTON &
SUTCLIFFE LLP

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By: 

Kurt T. Mulville, Reg. No. 37,194

4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Phone: 949/567-6700, ext.7740
Fax: 949/567-6710

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 36-37, 39 – 42 as follows:

36. (Amended) A nutritional supplement composition comprising:
a sealed container containing a solid granular, dry admixture wherein said admixture is comprised of dried, viable [Lactobacilli] bacteria of genus Lactobacill[i]us,
non-living, dried Brewer's or Baker's yeast in an amount comprising between about 2.5% and about 20% of the total mass of the composition, and
a protein concentrate selected from the group consisting of whey protein, soy protein, and animal protein concentrates.

37. (Amended) The composition of claim 36, wherein the genus Lactobacill[i]us bacteria is a species selected from the group of [genera or species] consisting of [strains] *Lactobacillus acidophilus*, *Lactobacillus bulgaricus*, *Lactobacillus casei* [*Lactobacillus germentum*,] *Lactobacillus helveticus*, *Lactobacillus bifidus*, *Lactobacillus lactis*, *Lactobacillus delbrueckii*, *Lactobacillus thermophilus*, [*Lactobacillus fermenti*,] *Lactobacillus coryniformis*, *Lactobacillus curvatus*, *Lactobacillus buchneri*, *Lactobacillus fermentum*, *Lactobacillus viridescens*, *Lactobacillus amylovorus*, *Lactobacillus amylophilus*, *Lactobacillus pentosaceus*, [*Lactobacillus salivaro*es,] *Lactobacillus brevis*, *Lactobacillus leichmannii*, *Lactobacillus plantarum*, and *Lactobacillus cellobiosus*.

VERSION TO SHOW CHANGES MADE

39. (Amended) The composition of claim 36, wherein the viable dried bacteria component comprises from about 0.25% to about 5.0% of the total mass [dry weight] of the composition.

40. (Amended) The composition of claim 36, wherein the non-living dried yeast component comprises from about 3.0% to about 12.5% of the total mass [dry weight] of the composition.

41. (Amended) The composition of claim 36, wherein the protein component comprises from about 50% to about 97% of the total mass [dry weight] of the composition.

42. (Amended) The composition of claim 36, wherein the protein component comprises from about 75% to about 96% of the total mass [dry weight] of the composition.